In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-486

(to be published)

VIVIEN LEE,	*	Chief Special Master Corcoran
Petitioner,	*	Filed: June 16, 2023
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Amy A. Senerth, Muller Brazil, LLP, Drescher, PA, for Petitioner.

Camille M. Collett, U.S. Department of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION[1]

On April 3, 2018, Vivien Lee filed a petition for compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program").[2] Petitioner alleges that she suffered a shoulder injury related to vaccine administration ("SIRVA") as a result of an influenza ("flu") vaccine she received in her left shoulder on January 12, 2017. Petition (ECF No. 1) at 1. The matter

[1] The parties may object to the published Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire Decision will be available to the public in its current form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-10–34 (2012)) (hereinafter "Vaccine Act" or "the Act"). All subsequent references to sections of the Vaccine Act shall be to the pertinent subparagraph of 42 U.S.C. § 300aa.

was originally assigned to the "special processing unit" (the "SPU"), but transferred out after the parties were unable to settle the claim.

I proposed (after the case's re-transfer to me in February 2022) that the matter could reasonably be decided on the record, and the parties have offered briefs in support of their respective positions. Petitioner's Brief, dated May 31, 2022 (ECF No. 35) ("Br."); Respondent's Brief, dated September 2, 2022 (ECF No. 38) ("Resp."). Having reviewed the medical records, multiple expert reports, and the parties' briefs, I hereby deny entitlement, for the reasons set forth below.

I. Factual Background

On January 12, 2017, Petitioner received the flu vaccine in her left shoulder at a local pharmacy. Ex. 1 at 3. There are no further records from that month relevant to this claim, and no contemporaneous evidence of a reaction to this vaccination.

A little less than a month later, on February 9, 2017, Petitioner went to her primary care provider, Dr. Jose Burbano, complaining of left shoulder and arm pain. Ex. 2 at 13. This record—the first document specifying a potential vaccine injury—is facially inconsistent as to the timing of onset. On the one hand, the record memorializes Petitioner's statement that her "left shoulder pain started *after* she had a flu shot that she thinks was administered incorrectly. She felt the pain *immediately*, like the nerve was hit." *Id*. at 13 (emphasis added). However, it also states before this description (and in "all caps" as well) that "PT STATES THAT IT STARTED AFTER SHE GOT HER FLU SHOT 1/12/17 ABOUT 4 DAYS AFTER". *Id.* The record of this visit additionally noted that onset was "1 month ago"—a timeframe that is roughly consistent with either immediate onset or four days later. *Id.*

Upon examination, Petitioner exhibited decreased range of motion and tenderness to palpation. Ex. 2 at 14. Dr. Burbano suspected rotator cuff syndrome and prescribed a topical treatment for the pain. *Id*. at 1–3. Additionally, Dr. Burbano noted that he "do[es] not think this is due to the flu shot." *Id*. at 14.

Five days after this visit to Dr. Burbano, on February 14, 2017, Petitioner presented to an Orthopedics and Sports Medicine Clinic with "lateral left shoulder pain that she believes is attributed to a flu shot that she received on January 12, 2017." Ex. 3 at 57, 66. Petitioner reported immediate pain following the injection, that the injection site felt hard the following day, and that "[s]ince that time, she has noted radiating pain *down her entire arm that also extends down her back*." *Id*. at 57 (emphasis added). Petitioner also reported "associated decreased sensation and numbness in her left fingers and wrist." *Id*. at 58. Upon examination, Michael Schwartz, M.D., noted decreased range of motion, tenderness at trapezius/deltoid, and decreased left shoulder

strength. *Id*. Dr. Schwartz's impression was left shoulder pain, and he recommended a neurology referral and a steroid injection—both of which Petitioner rejected. *Id*.

Petitioner thereafter had a physical therapy ("PT") evaluation on February 23, 2017, and subsequently received treatment for her left shoulder pain. Ex. 3 at 54–56. It was now recommended that Petitioner attend biweekly therapy session for four to twelve weeks. *Id*. at 55. She returned to Dr. Schwartz for a follow-up appointment on March 23, 2017, reporting continued left shoulder pain despite PT, but also noted that the pain radiated into her neck, arm, and hand. *Id*. at 38. Concerned that Petitioner's condition could be cervical, Dr. Schwartz ordered an MRI of her left shoulder, and it was performed that same day. *Id*. at 36, 39. The results revealed a mild to moderate supraspinatus tendinosis, moderate distal infraspinatus tendinosis, mild strain to distal teres minor myotendinous junction, mild subdeltoid bursitis, and mild to moderate osteoarthritic AC joint. *Id.* at 65.

On March 30, 2017, Petitioner followed-up with Dr. Schwartz. Ex. 3 at 36. She reported that her left shoulder symptoms remained unchanged, and Dr. Schwartz noted no structural pathology, expressing doubt that her arm pain and the swelling/stiffness in her hand correlated anatomically. *Id*. at 37. Dr. Schwartz considered the possibility of complex regional pain syndrome and referred Petitioner to a pain management specialist. *Id*. But he did not offer an opinion as to the possibility that the vaccine was causal, referring Petitioner back to Dr. Burbano for such matters. *Id*.[3]

On April 11, 2017, Petitioner saw Dr. Aine McKenzie, a specialist in pain management, with complaints of left arm pain/weakness/numbness/tingling that began in January 2017 since receiving her flu vaccination. Ex. 3 at 31. Petitioner reported her pain level ranging from three to eight out of ten. *Id*. Upon examination, Petitioner exhibited tenderness to the left side of her neck as well as decreased strength in her extremities on both sides. Dr. McKenzie diagnosed Petitioner with cervicalgia, left cervical radiculopathy, left upper limb carpal tunnel syndrome, and cervical spine ligament sprain. *Id*. at 30.

Petitioner had a C-spine MRI performed on May 8, 2017, which revealed some disc desiccation from C2-3 through C6-7, some posterior annular fissuring at C5-6, and shallow posterior central disc bulge at C3-4. Ex. 3 at 62. She underwent EMG[4] testing later that month, and it did not confirm the presence of left median sensory neuropathy. *Id.* at 60. Petitioner saw Dr.

[3] This medical record also contains reference to the alleged fact that at this time, "the subacromial injection did not offer any relief"—although there is no prior recorded evidence of Petitioner receiving any kind of steroidal injection intended to treat her pain. Ex. 3 at 37. I cannot therefore credit this representation.

[4] Electromyography (EMG) "measures muscle response or electrical activity in response to a nerve's stimulation of the muscle. The test is used to help detect neuromuscular abnormalities." *Electromyography (EMG)*, Johns Hopkins Medicine, https://www hopkinsmedicine.org/health/treatment-tests-and-therapies/electromyography-emg (last visited June 16, 2023).

McKenzie again on May 25, 2017, complaining of neck pain that she stated was radiating to her left arm. *Id.* at 25. Dr. McKenzie proposed that Petitioner attempt some conservative treatments, like ice/heat. *Id.* at 25–27.

After this point, Petitioner continued physical therapy through July 24, 2017. Ex. 3 at 54–56. She also appears to have visited Dr. MacKenzie again in July 2017, who diagnosed her with ulnar neuritis and recommended continued physical therapy. *Id.* at 28–30. No other records were filed relevant to the injury.

The record also contains two witness statements from Petitioner. *See* Affidavit, dated Mar. 19, 2018, filed as Ex. 4 (ECF No. 1-7) ("Lee Aff."); Supplemental Declaration,[5] dated July 16, 2019, filed as Ex. 5-2 (ECF No. 22-2) ("Supp. Lee Aff."). The first of Petitioner's witness statements provides no detail about onset time at all. Lee Aff. at 1 ¶¶ 2–4. The second, however, maintains that Petitioner experienced immediate pain—but also that the pain continued into the next day. Supp. Lee Aff. at 1. But the second affidavit says nothing about the four-day onset reported in the February 9, 2017 record, nor does it explain why the document sets forth that onset if it was inaccurate.

II. Expert Reports

A. *Naveed Natanzi, D.O., for Petitioner*

Dr. Natanzi is a specialist in physical medicine and rehabilitation and prepared one written report for Petitioner. Report, dated Aug. 28, 2019, filed as Ex. 6 (ECF No. 24-2) ("Natanzi Rep."). Dr. Natanzi opined that the flu vaccine Petitioner received in January 2017 was more likely than not causative of a left shoulder SIRVA. Natanzi Rep. at 10.

Dr. Natanzi obtained his undergraduate degree in biological studies at the University of California, Santa Barbara, and his osteopathic degree from Western University of Health Sciences. Curriculum Vitae, filed as Ex. 7A-1 (ECF No. 24-3) ("Natanzi CV") at 2. Thereafter, he completed an internship at Downey Regional Medical Center, followed by a residency and fellowship in physical medicine and rehabilitation at the University of California, Irvine. *Id*. at 1. He is an Attending Physician in Interventional Pain Management at Pasadena Rehab Institute as well as the Founder of Interventional Regenerative Sports and Spine Medicine at Regenerative Sports and Spine Institute in Encino, CA. *Id*. Dr. Natanzi is board certified by the American Academy of Physical Medicine and Rehabilitation. *Id*.

Dr. Natanzi provided a brief overview of Petitioner's present illness and relevant medical history. Natanzi Rep. at 7. Based on his evaluation of the records and certain medical literature,

[5] Although this witness statement is labeled as an affidavit, it is not notarized.

Dr. Natanzi opined that Petitioner's immediate shoulder pain with decreased range of motion, and the absence of any pre-existing neck or shoulder issues, was sufficient to meet the criteria for a SIRVA-mediated injury. Natanzi Rep. at 7. Moreover, Dr. Natanzi pointed to Petitioner's MRI findings, which he maintained revealed "clinically significant subacromial bursitis and supraspinatus tendinosis with bursal sided change"—all of which are commonly seen with SIRVA. *Id.*

Dr. Natanzi then addressed Respondent's assertion of a possible alternative diagnosis—cervical radiculopathy. Natanzi Rep. at 7–8. He opined that developing acute cervical radiculopathy post-injection "would be anatomically inexplainable, and exceedingly improbable," in comparison to the likelihood of SIRVA. *Id.* Moreover, although cervical radiculopathy is often accompanied by pain and restriction in the cervical section of the spine (meaning in the neck), the common MRI findings (i.e., nerve root/cord compression) for cervical radiculopathy were not evident from Petitioner's medical records. *Id.*; Ex. 3 at 62. Thus, Dr. Natanzi opined that Petitioner's clinical presentation and symptoms more likely reflected a SIRVA than an atypical presentation of acute cervical radiculopathy. *Id.*

Dr. Natanzi also discussed the temporal course of Petitioner's symptoms, maintaining that it was consistent with a SIRVA injury. Natanzi Rep. at 9. It was in this case likely that an inadvertent over-penetration of the vaccination needle (due to the standing position of the injector and seated position of Petitioner) into her left shoulder resulted in the overpenetration of her bursal and supraspinatus tendons. *Id.*; *See* I. Cook, *An Evidence Based Protocol for the Prevention of Upper Arm Injury Related to Vaccine Administration (UAIRVA)*, 7 Human Vaccines 845, 847 (2011), filed as Ex. 7E-1 (ECF No. 24-7) (discussing proper protocol to avoid intra-bursal or intra-articular injection and finding the shoulder abducted and at the midpoint of the deltoid is ideal location for vaccine administration); S. Atanasoff et al, *Shoulder Injury Related to Vaccine Administration (SIRVA)*, 28 Vaccine 8049, 8052 (2010), filed as Ex. 7F-1 (ECF No. 24-8) (finding that concurrent seating positions for the administrator of a vaccine and the recipient may help minimize the risk of the injection being too high). Subsequently, Petitioner experienced immediate and radiating pain and discomfort in her left shoulder, also evidenced by limited range of motion that same day. *Id.* The vaccine interacted with Petitioner's naturally-occurring antibodies from a prior vaccination, Dr. Natanzi proposed, which ultimately resulted in a prolonged inflammatory response leading to left shoulder pain and dysfunction. *Id.*

In support of the foregoing, Dr. Natanzi relied on several items of literature describing approximately 80 cases in which an immune mediated inflammatory reaction is seen as a result of a vaccine. *See, e.g.*, M. Bodor & E. Montalvo, *Vaccination-Related Shoulder Dysfunction*, 25 Vaccine 585, 586 (2007), filed as Ex. 7C-1 (ECF No. 24-5) (hypothesizing that the vaccine was injected into the subdeltoid bursa in both of the study's patients, causing a robust inflammatory mediated response); M. Barnes et al, *A "Needling" Problem: Shoulder Injury Related to Vaccine*

Administration, 25 J. Am. Bd. Fam. Med. 919, 919 (2012), filed as Ex. 7G (ECF No. 24-9) ("Barnes") (describing single case of woman who developed acute left shoulder pain and severe restrictions in range of motion following flu vaccine); L.H. Arias et al, *Risk of Bursitis and Other Injuries and Dysfunctions of the Shoulder following Vaccinations*, 35 Vaccine 4870, 4871–72 (2017), filed as Ex. 7J-1 (ECF No. 24-12) (finding 45 cases of bursitis and other shoulder injuries following vaccination (a majority of which involved the influenza and pneumococcal vaccines)). These findings were consistent with Petitioner's medical records and the views of treating physicians. Natanzi Rep. at 10.

Dr. Natanzi concluded his report by stating that Petitioner's injury met the criteria for SIRVA, noting that her symptoms not only closely mimicked what is described in the relevant medical literature, but based upon the temporal relationship of the onset of symptoms following receipt of vaccination, and the absence of any prior left shoulder dysfunction. Natanzi Rep. at 10.

B. *Brian Feeley, M.D., for Respondent*

Dr. Feeley is an orthopedic surgeon and prepared one written report for Respondent. Report, dated Jan. 16, 2020, filed as Ex. A (ECF No. 30-1) ("Feeley Rep."). Dr. Feeley opined that Petitioner's left SIRVA was most likely not caused by her receipt of the flu vaccine, but instead due to alternative causes. Feeley Rep. at 8.

Dr. Feeley obtained his undergraduate degree in biological sciences and his medical degree from Stanford University. Curriculum Vitae, filed as Ex. B (ECF No. 30-2) ("Feeley CV") at 1. Thereafter, he completed his residency in Orthopedic Surgery at UCLA, followed by a fellowship in Sports Medicine and Shoulder Surgery at the Hospital for Special Surgery in New York. *Id.* Since then, Dr. Feeley has been practicing orthopedic surgery at the University of California, San Francisco and is currently a Professor in Residence. Feeley CV at 1; Feeley Rep. at 1. He is board certified by the American Board of Orthopedic Surgery and has published over 150 peer-reviewed manuscripts, review papers and book chapters. Feeley CV at 23–37; Feeley Rep. at 1. Over the course of his career, Dr. Feeley has examined and treated patients with both shoulder and knee problems, including patients with "all types of shoulder pathologies." Feeley Rep. at 1.

To begin, Dr. Feeley provided a brief overview of Petitioner's medical history followed by a quick summary of common shoulder pathologies such as frozen shoulder, cervical radiculopathy, rotator cuff impingement, tendonitis, and rotator cuff tears. Feeley Rep. at 2–6. Dr. Feeley opined that Petitioner most likely suffered adhesive capsulitis and cervical radiculopathy—noting that Petitioner's medical records suggested that she carried risk factors for adhesive capsulitis, including hyperlipidemia, and that her clinical presentation and course included hallmark signs for such. Feeley Rep. at 6. Moreover, if Petitioner had been suffering from some rotator cuff pathology (i.e., impingement syndrome or a partial thickness rotator cuff tear) she would have been more

responsive to a steroid injection. *Id.* Additionally, Dr. Feeley noted that Petitioner suffered from cervical radiculopathy based on her symptoms and clinical presentation—pain and numbness shooting down into the hand, a positive Spurling's test,[6] and limited cervical range of motion—even though her MRI findings were admittedly inconsistent with that diagnosis. *Id.*

Dr. Feeley then briefly discussed the limited nature of current scientific literature linking "vaccines and/or the act of vaccination to shoulder injuries—and adhesive capsulitis particularly." Feely Rep. at 6. For example, Dr. Feeley referenced an article that looked at shoulder problems following vaccination and identified 45 reported cases (37 of those were drawn from a systematic review of the literature while the remaining eight from scrutiny in the Spanish Pharmacovigilance System Database). *Id.* at 6–7; L.H. Martín et al, *Risk of Bursitis and Other Injuries and Dysfunctions of the Shoulder following Vaccinations*, 35 Vaccine 4870, 4870 (2017), filed as Ex. A8 (ECF No. 37-8) ("Martín"). Of the 45 cases identified by Martín, a majority of the people who reported post-vaccination shoulder injuries were women, the diagnosis was bursitis, and the onset was within four days, with most symptoms presenting in the first 48 hours post-vaccination. *Id.* at 4871–73.

Additionally, Dr. Feeley referenced several items of literature that suggested a link between vaccines and frozen shoulder. Feeley Rep. at 7; *See* Z. Saleh et al, *Onset of Frozen Shoulder following Pneumococcal and Influenza Vaccinations*, 14 J. of Chiropractic Med. 285 (2015), filed as Ex. A9 (ECF No. 37-9) ("Saleh") (identifying three cases of frozen shoulder following the pneumococcal and/or flu vaccinations with an acute onset occurring within 24 hours); I. Degreef & P. Debeer, *Post-Vaccination Frozen Shoulder Syndrome. Report of 3 Cases*, 112 Acta Chir. Belg. 447, 448 (2012), filed as Ex. 7L-2 (ECF No. 24-14) (documenting severe frozen shoulder in three patients within hours after receiving a flu vaccine, Hepatitis A vaccine, and tetanus vaccine). By contrast, Dr. Feeley maintained, literature established no documented courses of cervical radiculopathy resulting from vaccination, despite how commonly individuals suffer from cervical radiculopathy. Feeley Rep. at 7.

Dr. Feeley also criticized several specific aspects of Dr. Natanzi's opinion. Feeley Rep. at 7. For example, he disagreed with Dr. Natanzi's contention that Petitioner's MRI results were consistent with a clinically significant bursitis, deeming that diagnosis inaccurate. *Id.* He highlighted as significant Petitioner's negative impingements signs during her initial presentation to her orthopedic surgeon as inconsistent with bursitis. *Id.* at 7; Ex. 3 at 65. Petitioner's inconsistent loss of range of motion also should have been relatively minimal if bursitis accurately described her condition. Feeley Rep. at 6,7. And Petitioner's MRI findings (showing mild tendinosis, but no other significant findings) were not consistent with SIRVA either. *Id.*; Ex. 3 at 64.

[6] "Spurling test" is where "the examiner presses down on the top of the head while the patient rotates the head laterally and into hyperextension; pain radiating into the upper limb ipsilateral to a rotation position of the head indicates radiculopathy." *Spurling test*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=112983 (last visited June 16, 2023).

While Dr. Feeley accepted Dr. Natanzi's theory generally about SIRVA as vaccine-associated, he maintained that there are other, more plausible reasons why a person might experience comparable symptoms. Feeley Rep. at 8. For example, Petitioner had experienced immediate pain in her shoulder and neck—but such kinematic changes would take a considerable amount of time to develop. *Id.* Moreover, despite Petitioner's MRI findings showing normal results with no active compression, several articles established that nerve compression can occur by a dynamic process, and thus a lack of MRI findings did not eliminate the possibility that the Petitioner actually suffered from dynamic radiculopathy. *Id.*; *See also* H. Mao et al, *Dimensional Changes of the Neuroforamina in Subaxial Cervical Spine during In Vivo Dynamic Flexion-Extension*, Spine J. 7 (2016), filed as Ex. A11 (ECF No. 37-11) (using cervical dynamic MRI to demonstrate a loss of neuroforaminal space, including in asymptomatic patients); T. Kitagawa et al, *Morphologic Changes in the Cervical Neural Foramen due to Flexion and Extension: In Vivo Imaging Study*, 29 Spine 2821, 2824 (2004), filed as Ex. A12 (ECF No. 39-1) (showing dynamic neural foraminal changes on CT images in asymptomatic subjects).

With respect to the timing of a SIRVA-based reaction, Dr. Feeley maintained that a majority of studies show onset of pain within the first 72 hours. Barnes at 1919; Saleh at 286–87. While Dr. Feeley acknowledged that Petitioner reported acute pain, he noted that the record also established that Petitioner initially reported that her pain began *four days* after receiving the flu vaccine—a timeframe well outside of what is medically accepted for SIRVA claims. Feeley Rep. at 8. Similarly, Dr. Feeley laid out several notable facts that explained the absence of a logical sequence of cause and effect. Thus, Petitioner did not exhibit any signs or symptoms of bursitis, she had several risk factors for adhesive capsulitis, the treatment of her bursitis proved ineffective, and treaters proposed she had experienced cervical radiculopathy, which is likely explained by her dynamic compression of her cervical spine. *Id.* At bottom, Dr. Feeley saw evidence both that Petitioner exhibited symptoms of adhesive capsulitis and cervical radiculopathy—but not SIRVA. *Id.* at 8.

III. Procedural History

As noted above, the claim was initiated in the spring of 2018. This matter was originally assigned to the SPU, since it alleged a SIRVA injury and thus appeared to be likely to settle. But Respondent filed a Rule 4(c) Report in May 2019, arguing that Petitioner had not met the Table criteria. ECF Nos. 18 and 20 (Report amended). Early that fall, Petitioner filed Dr. Natanzi's report in an effort to bulwark her claim, but Respondent subsequently indicated that he would be defending the matter and offering an expert report of his own. ECF No. 26.

Accordingly, the case was transferred out of SPU and assigned to a special master, and Respondent filed Dr. Feeley's report in January 2020. In the winter of 2022, the matter was reassigned to my non-SPU docket, and I subsequently set the briefing schedule for a ruling on the

record. *See* Docket Entry Order, dated March 10, 2022. The claim is now fully briefed and ripe for resolution.

IV. Parties' Respective Arguments

Petitioner argues that she has presented a sound mechanism for SIRVA caused by vaccination, and that there is a clear preponderance of evidence that her flu shot more likely than not caused her symptoms. Br. at 14. Petitioner maintains that her medical records and affidavit testimony support a finding of immediate onset of left shoulder pain post-vaccination—noting several instances in which she reported feeling pain immediately following receipt of the flu vaccine to her treating physicians. *Id.* at 10. Petitioner further maintains that the records establish that her pain was limited to her left shoulder despite several complaints suggesting that Petitioner experienced pain beyond that of her left shoulder. *Id.* at 11.

Respondent, in contrast, maintains that Petitioner has failed to preponderantly establish that she suffered from a SIRVA, noting that the medical records do not support onset of pain within 48 hours of vaccination, but instead indicate that Petitioner reported shoulder pain beginning four days post-vaccination. Resp. at 8–9. Respondent also argues that Petitioner suffered symptoms that were more likely than not caused by another condition or abnormality present (i.e., cervical radiculopathy and adhesive capsulitis)—which, according to Dr. Feeley, can be better explained by Petitioner's dynamic compression of her cervical spine. *Id.* at 10, 12.

V. Applicable Legal Standard

A. *Standards for Vaccine Claims*

To receive compensation in the Vaccine Program, a petitioner must provide either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time, or in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. §100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[7] In this case, Petitioner asserts a Table claim, along with a causation claim in the alternative. Br. at 9.

[7] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. App'x 712 (Fed. Cir. 2014); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13–159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. V. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury." Each *Althen* prong requires a different showing and is discussed in turn along with the parties' arguments and my findings.

Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

However, the Federal Circuit has *repeatedly* stated that the first prong requires a preponderant evidentiary showing. *See Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1360 (Fed. Cir. 2019) ("[w]e have consistently rejected theories that the vaccine only "likely caused" the injury and reiterated that a "plausible" or "possible" causal theory does not satisfy the standard"); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1350 (Fed. Cir. 2010). This is consistent with the petitioner's ultimate burden to establish his overall entitlement to damages by preponderant evident. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted). If a claimant must *overall* meet the preponderance standard, it is logical that they be required also to meet each individual prong with the same degree of evidentiary showing (even if the *type* of evidence offered for each is different).

Petitioners may offer a variety of individual items of evidence in support of the first *Althen* prong, and are not obligated to resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). No one "type" of evidence is required. Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Andreu*, 569 F.3d at 1380. Nevertheless, even though "scientific certainty" is not required to prevail, the individual items of proof offered from the "can cause" prong must *each* reflect or arise from "reputable" or "sound and reliable" medical science. *Boatmon*, 941 F.3d at 1359–60.

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injury party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do no *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot.*

for reviewed den'd, 100 Fed. Cl. 344, 356—57 (2011), *aff'd without opinion*, 475 F. App'x. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2001), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Law Governing Analysis of Fact Evidence*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucura*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs.*, 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V,

2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucura v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 545 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations I which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exists. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical

records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). Under *Daubert*, the factors for analyzing the reliability of testimony are:

> (1) Whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Synder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too

great an analytical gap between the data and the opinion proffered." *Synder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs.*, No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review denied*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App's 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluation petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed some items of medical and scientific literature in this case, but not every filed item factors into the outcome of this Decision. While I have reviewed all the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.*, 527 F. Sppx. 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

E. *Standards for Ruling on the Record*

I am resolving Petitioner's claim on the filed record, and the parties have not challenged my determination to do so. Br. at 2; Resp. at 1. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs.*, 945 F.3d 1362 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. Servs.*, No. 02–472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs.*, 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90–882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

I. Petitioner Has Not Preponderantly Established the Elements of a Table SIRVA Claim

The Table Qualifications and Aids to Interpretation ("QAI") for SIRVA injuries provide details relevant to what a petitioner must demonstrate to succeed on a Table SIRVA. *See* 42 C.F.R. § 100.3(b)(10). The Table QAIs for SIRVA require: (1) no history of pain, inflammation, or dysfunction of the affected shoulder prior to intramuscular vaccine administration; (2) pain occurring within 48 hours of the vaccine administration; (3) pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and (4) no other condition or abnormality is present that would explain Petitioner's symptoms. *Id.* Although these elements do not formally apply to a causation-in-fact SIRVA claim, they provide some insight into the factors relevant even outside the Table.

Here, it is preponderantly "more likely than not" that Petitioner cannot satisfy one important Table element: onset beginning within 48 hours and then persisting. Admittedly, the document most relevant to the question contains contradictory information, including statements that could be deemed to simultaneously support a 48-hour onset (to the extent Petitioner reported immediate pain) and one occurring later. But ultimately I find that evidence preponderates more in favor of an onset *longer than four days* post-vaccination—thus supporting dismissal.[8]

The February 9, 2017 record at issue *clearly and unequivocally* identifies an onset beginning four days post-vaccination—in all capital letters, no less. Ex. 2 at 13. While it also contains a report of an immediate *feeling* of pain, that memorialized statement is not connected to statements suggesting that this pain *continued* thereafter. Rather, this part of the February 9, 2017 record is reasonably construed to mean that the initial pain from vaccination was *momentary* and *transitory*—with more than two days passing before true onset (thereafter characterized by persistent and ongoing pain) occurred. This is inconsistent with how onset is understood for SIRVA claims: persistent pain must *begin* within 48 hours of vaccination. *Bulman v. Sec'y of Health & Hum. Servs.*, No. 19-1217V, 2021 WL 4165349, at *4 (Fed. Cl. Spec. Mstr. Aug. 12, 2021).

The fact that this record implicates the vaccination generally does not alter my construction of the record's contents. Petitioner may have *suspected* that her immediate, momentary pain was unusual, and reasonably felt that the vaccination explained it as well as her later symptoms. Indeed, that is a fair basis for a *non-Table* causation claim (which is discussed below). But for Table

[8] There are other reasonable questions pertaining to the strength of the Table claim, such as whether Petitioner's injury was limited to her shoulder, and/or whether it meets the definitional criteria for SIRVA. But a Table claim must satisfy *all* criteria relevant to it, so I do not delve into Petitioner's success in establishing all other elements (although they bear on causation, as discussed below). 42 C.F.R. § 100.3(c)(10)(i)(iii-iv).

purposes, more is required than a single, passing instance of immediate pain after vaccination *followed* by an actual onset several days later. For purposes of a SIRVA injury, onset of persistent pain must begin in the defined period, and cannot arrive outside of it, even if the claimant also reports an "immediate" moment of pain, as here. The same thinking on onset applies generally to all vaccine injury claims; evidence of a transitory, close-in-time vaccine reaction reported by a claimant is not necessarily when a claimant's actual injury began. *Wetz v. Sec'y of Health & Hum. Servs.*, No. 07-633V, 2012 WL 3967106, at *3 (Fed. Cl. Spec. Mstr. May 31, 2012) ("[i]dentification of either the first symptom or manifestation of onset, however, does not require a doctor's diagnosis . . . [n]or does the identification of signs of an injury turn on the subjective knowledge of petitioner") (citations omitted).

Other aspects of the record outweigh my construction of the first treatment record from February 2017. While Petitioner thereafter consistently associated her shoulder and other pain to the vaccination, she did not indicate in other records an immediate onset, or contradict the four-day post-vaccination onset memorialized in the first record from February 9th. The subsequent reports of a vaccine-associated injury do not make it more likely that the injury began immediately, or 48 hours after. Her witness statements also do not provide a reason to ignore the onset statement set forth in this first record. Only Petitioner's supplemental statement alleges an earlier onset, persisting from the moment of vaccination. But it lacks sufficient corroboration with *other* records or statements to deem it more reliable (and/or deserving of weight). Moreover, the supplemental statement was executed in July 2019—approximately 30 months post-vaccination and after the issue of onset was raised as an issue in this case. And Petitioner has otherwise offered no explanation for how the four-day onset reference in this record should be construed differently, or interpreted other than how I propose. Indeed, although her brief references the four-day onset statement, she does not argue as to why other evidence that would support an immediate onset outweighs it. *See* Br. at 10. For this reason, the Table claim is dismissed.

II. Petitioner Has Not Preponderantly Established a Causation-in-Fact Claim

Table SIRVA claims are often transferred out of the SPU—either because a complex fact question is raised about a Table element, requiring development or even expert input, or where it appears a "non-Table" version of the claim might succeed. *See Johnson v. Sec'y of Health & Hum. Servs.*, No. 20-1008V, 2022 WL 1613647 (Fed. Cl. Spec. Mstr. Apr. 7, 2022). Although Respondent has indirectly suggested (in the context of defending other claims) the view that *any* SIRVA injury is impossible in an off-Table context, OSM's practice has been to at least afford claimants the chance to try to prove otherwise. *Morris v. Sec'y of Health & Hum. Servs.*, No. 19-1570V, 2021 WL 6504390, at *5 (Fed. Cl. Spec. Mstr. Dec. 15, 2021) (finding that Petitioner likely still had a viable non-Table claim, despite the absence of preponderant evidence establishing onset within 48 hours). At a minimum, some kinds of arm and shoulder injuries might reflect a nonspecific kind of "neuropathy" that could reasonably be posited to reflect a vaccine injury, even

if the facts did not allow the conclusion that the injury was more likely than not a SIRVA as the term is defined by the Table.

Non-Table causation claims are subject to the three-prong test established by the Federal Circuit in *Althen*, 418 F.3d at 1278: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury." Here, I find that these elements have not been preponderantly met.

First, I do not find that Petitioner has established an injury that could be deemed vaccine-associated. *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1346 (Fed. Cir. 2010). The record does not support an injury that could be classified as SIRVA. As noted earlier, Petitioner exhibited several risk factors for adhesive capsulitis, including hyperlipidemia, making it a likely source of her shoulder pain distinguishable from SIRVA. Feeley Rep. at 6. Moreover, her clinical presentation also suggested the presence of an injury more akin to adhesive capsulitis and cervical radiculopathy[9] (and MRI evidence was inconclusively supportive of either proposed diagnosis). *Id*. The medical history also supports the conclusion that the injury was cervical in nature, with that diagnosis made by several treaters. And the constellation of symptoms Petitioner experienced do not reflect the more shoulder-specific complaints that suggest a SIRVA. A claimant cannot succeed simply by referencing post-vaccination *symptoms* she may have experienced, without also providing a likely injury that would *feature* those symptoms. *P.M. v. Sec'y of Health & Hum. Servs.*, No. 16-949V, 2019 WL 5608859, at *27 (Fed. Cl. Spec. Mstr. Oct. 31, 2019). Dr. Natanzi's opinion largely goes to whether the injury *was* a SIRVA, but the nature of the injury that the record best supports is not consistent with what is known about the association between vaccines and *SIRVA*.

Second, Petitioner has not demonstrated that the flu vaccine she received could cause a non-SIRVA radiculopathy characterized by the presenting features and symptoms reflected in the medical record. Because Dr. Natanzi's focus was on providing support for the vaccine-SIRVA association (which, at least in the Table sense, can be credibly linked to vaccinations of all kinds), he did not at all address whether an alternative injury like cervical radiculopathy could be vaccine-caused. But because I determined that Petitioner *did not* likely experience a SIRVA injury, the need for a reliable and persuasive theory associating vaccination to what Petitioner suffered from was greater—but not supplied by the filed expert report. The report does not establish that Petitioner's more-likely cervical radiculopathy could be, or was, vaccine-caused.

[9] Cervical radiculopathy is described as a compression or structural issue associated with congenital or degenerative disease rather than an inflammatory condition. *See, e.g.*, *Devonshire v. Sec'y of the Dep't of Health & Hum. Servs.*, No. 99-031V, 2006 WL 2970418, at *18 (Fed. Cl. Spec. Mstr. Sept. 28, 2006) *aff'd*, *Devonshire v. Sec'y of Dep't of Health & Hum. Servs.*, 76 Fed. Cl. 452 (2007).

Finally, the "did cause" element was not satisfied. There is no treater support, for example, in the medical record of a connection between the vaccination and Petitioner's subsequent pain and other complaints; instead, treaters either disputed an association, or declined to opine on whether any association existed. *See, e.g.*, Ex. 2 at 14; Ex. 3 at 37. And nothing else in the record (beyond the obvious temporal association between vaccination and start of symptoms) suggests that the vaccine had initiated some process leading to Petitioner's cervical radiculopathy.[10]

III. The Case Was Properly Decided Without a Hearing

In ruling on the record, I am choosing not to hold a hearing—a determination that the parties largely accepted. Br. at 2; Resp. at 1. Determining how best to resolve a case is a matter that lies generally within my discretion, but I shall explain why I determined that a hearing was unnecessary.

Prior decisions have recognized that a special master's discretion in deciding whether to conduct an evidentiary hearing "is tempered by Vaccine Rule 3(b)," or the duty to "afford[] each party a full and fair opportunity to present its case." *Hovey*, 38 Fed. Cl. at 400–01 (citing Rule 3(b)). But that rule also included the obligation of creation of a record "sufficient to allow review of the special master's decision." *Id*. Thus, the fact that a claim is legitimately disputed, such that the special master must exercise his intellectual faculties to decide a matter, it not itself grounds for a trial (for if it were, trials would be required in every disputed case). Special masters are expressly empowered to resolve fact disputes without a hearing—although they should only so act if a party has been given the proper "full and fair" chance to prove their claim.

This matter was reasonably decided on the papers. The claim presented a discrete and limited fact pattern that was not overly complex to resolve despite the need for some expert input. Resolution of the Table claim turned on a single document, and while the remaining non-Table claim required balancing of more items of evidence, I was able to understand expert positions and evaluate the issue without requiring live testimony. Resolving the claim through ruling on the record expedited its conclusion, and in a manner that was fair to all sides.

CONCLUSION

A Program entitlement award is only appropriate for claims supported by preponderant evidence. Here, Petitioner has not made such a showing. She is therefore not entitled to compensation.

[10] I acknowledge, however, that the timeframe in which Petitioner's injury manifested is consistent with a variety of peripheral neuropathies, and thus the third *Althen* prong has been met under the relevant facts.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.[11]

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[11] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.